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## Parents' and young people's involvement in designing a trial of ventilator weaning

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## **ABSTRACT**

### **Parents' and young people's involvement in designing a trial of ventilator weaning**

**Background:** Consulting with users is considered best practice and is highly recommended in designing new trials. As part of our feasibility work, we undertook a consultation exercise with parents, ex-patients and young people prior to designing a trial of protocolised ventilator weaning.

**Aims:** Our aims were to 1) ascertain views on the relevance and importance of the trial; 2) determine the important parent/patient outcome measures; and 3) ascertain views on informed consent in a cluster randomised controlled trial .

**Methods:** We conducted audio-recorded face-to-face, telephone and focus group interviews with parents and young people. Data were content analysed to generate information to address our specific consultation objectives.

**Setting and participants:** The setting was the North West region of England. Sixteen participants were interviewed: two parents of PICU survivors; one PICU survivor; and 13 young people from the former Medicines for Children Research Network.

**Results:** The trial objectives were deemed important and relevant, and participants considered the most important outcome measure to be the length of time on ventilation. Parents and young people did not consider written informed consent to be a necessary requirement in the context of this trial, rather awareness of unit participation in the trial was important with the opportunity of opting out of data collection.

**Conclusions:** This consultation provided useful, pragmatic insights to inform trial design. We encountered significant challenges in recruiting parents and young people for this consultation exercise, and novel recruitment methods need to be considered for future work in this field.

**Relevance to clinical practice:** Patient and Public Involvement is essential to ensure that future trials answer parent-relevant questions and have meaningful outcome measures, as well as involving parents and young people in the development of healthcare services more generally.

# **Parents' and young people's involvement in designing a trial of ventilator weaning**

## **Introduction**

Patient and public involvement (PPI) in research brings benefits to society, because of its positive influence on the research study, in terms of patient recruitment, informed consent, feasibility, design and dissemination [Boote et al 2002; Edwards et al 2011]. Mindful of these benefits in the feasibility stage of designing a multicentre trial, we set out to engage PPI early on to ensure we were addressing patient relevant outcomes and to inform design and ethical requirements. The aim of this paper is to describe our experiences and the challenges of engaging parents, patients and young people in the development and design of a research trial about weaning mechanical ventilation and sedation in Paediatric Intensive Care Units (PICUs).

## **Background**

There are numerous ethical and political arguments for patient involvement in research based on values such as democracy, accountability and empowerment [Gradinger et al 2013; Stewart & Liabo 2012; Barber et al 2011]. Indeed, since 1996 the United Kingdom (UK) National Institute of Health Research has funded a project (INVOLVE) to engage public involvement in National Health Service, public health and social care research [NIHR INVOLVE]. The team at INVOLVE work in partnership with researchers, research commissioners and the public to build capacity and engagement, offering support and resources to assist that process. As a result, most funding bodies in the UK require researchers to provide evidence of patient

involvement when submitting research applications [Robinson et al 2012; NIHR RDS 2014; Boote et al 2002]. In the context of parental involvement in the design of paediatric research, parents of former critically ill children are a group that requires particular care and sensitivity when approaching them to engage in study design. Having a child admitted to an intensive care unit can be a life changing experience for many parents [Colville et al 2009] and the incidence of post-traumatic stress disorder is reported to be as high as 30% at 6-12 months after the event [Colville et al 2009; Balluffi et al 2004; Bronner et al 2010]. In addition, most children admitted to PICUs are less than 12 months old [PICANET 2013], meaning that many parents are relatively young, often have other children and are often working. All these factors may contribute to the lack of engagement of this group of parents with researchers. Unlike other disease-specific support groups, no national support groups specifically exist for these parents, although specific PICUs may offer on-going support. For many parents, their child's PICU admission will be a one-off event. As a result, it can be difficult to reach and engage parents in the design and conduct of trials conducted in the PICU environment, yet engagement is paramount when investigators are seeking funding for their trial. Increasing numbers of children (around 95%) now survive paediatric intensive care [PICANET 2013] and seeking PPI views on service provision and involvement in future research is becoming increasingly important. Most of the literature has described parental involvement in consultation and there is a distinct lack of literature describing the engagement of PICU survivors in any consultation process. In contrast, in non PICU settings, children are increasingly involved in developing healthcare services and consulting on research (Balen et al 2006 Newman et al 2012; Fleming et al 2012).

## **The proposed trial**

Mechanical ventilation (MV) is a common lifesaving therapy: worldwide 55% [Farias et al 2001] and in the UK 67% [PICANET 2013] of children admitted to a PICU require ventilator support. Most children are successfully weaned from the ventilator within 48 hours after admission [Newth et al 2009] and usually at first attempt [Farias et al 2001; Foronda et al 2011], but for others the weaning process is more difficult and protracted. Our recent paper reporting practice in this area in the UK [Blackwood & Tume 2015] highlighted a disjointed process that could potentially be improved by introducing a combined sedation and ventilator weaning protocol that engages all staff in the process. Beneficial effects of using weaning protocols in the paediatric setting have been reported in a recent systematic review [Blackwood et al 2013], but it is unknown if findings from the three included trials conducted in North America are generalisable to the UK. There is increasing clinical interest in using weaning protocols in the UK and therefore a need to evaluate their effectiveness in the UK setting.

Our proposed trial will compare a multidisciplinary team based weaning protocol with usual care, which we hypothesise will reduce the duration of mechanical ventilation in PICU. The intervention is an extension of usual practice that advocates earlier detection of the child's readiness to wean off ventilation and a challenging spontaneous breathing trial to test the ability to come off mechanical ventilation in combination with a reduction in sedative drugs. Earlier detection of readiness to discontinue mechanical ventilation and reducing sedation are considered important

patient-related outcomes by investigators of ventilation trials [Blackwood et al 2014], but we do not know if these outcomes are important to parents. We also do not know if parents consider optimising the weaning process as an important research topic. We are proposing to undertake a cluster randomised controlled trial (RCT) involving sequential implementation of the intervention to clusters (PICUs) over a number of time periods [Brown and Lilford 2006]. The intervention carries little or no risk to the child as it employs a weaning process based on best practice. The intervention involves a behavioural change in practice that will require training; hence a cluster RCT will avoid problems of contaminating the intervention that may occur with a parallel group RCT. We are planning to include all children requiring to be weaned from mechanical ventilation, but we are conscious that obtaining consent from all parents would place a disproportionate burden in terms of time and resources in relation to the perceived risk. Recent draft guidance from the NHS Health Research Authority [NHS Health Research Authority 2014] suggests that in trials such as this, the use of simplified means to obtain consent may be considered. However, we do not know the opinion of parents on this issue, therefore, we consulted with three sets of stakeholders: parents; ex-patients; and children and young people (who would not necessarily have experience of PICU) from a well-established Advisory Group within the paediatric tertiary centre. Our aim was to determine the acceptability of the trial to parents and children. Our objectives were to: 1) ascertain their views on the relevance and importance of the study, 2) determine parent/patient focused outcome measures and 3) ascertain their views on informed consent in a cluster RCT.

## Methods

### Approach

We undertook this consultation exercise between June and December 2014 in the North West region of England. To undertake this work, we obtained an 'Enabling Research Award' from the Health and Social Care, Public Health Agency, Research and Development (PHA R&D) Division, Northern Ireland, UK, which supports applications to the UK National Institute of Health Research (NIHR). Our approach to consultation was informed by the NHS Institute for Innovation and Improvement – Patient Perspectives

([http://www.institute.nhs.uk/quality\\_and\\_service\\_improvement\\_tools/quality\\_and\\_service\\_improvement\\_tools/patient\\_perspectives.html](http://www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/patient_perspectives.html)) and INVOLVE NHS National

Institute for Health Research – Involving Children and Young People

(<http://www.invo.org.uk/find-out-more/involving-children-and-young-people/resources-for-involving-children-and-young-people/>). We used a framework

that included establishing:

- An expert team to provide consultation (LT is a senior research fellow and paediatric nurse with >20 years PICU experience; JP is Consumer Liaison Officer for Medicines for Children Research Network (MCRN) and member of the Consumer Involvement Steering Group that acts as an expert forum to promote research interests and priorities of children, young people, parents and carers within MCRN.)
- Relevant stakeholders (parents, PICU survivors; children and young people)



- A relevant format for consultation and budget for alternative formats of recruitment (interview, poster, fliers)
- A realistic timescale
- Clear information and objectives
- Respondent agreement to opt-in to making their views publicly available.

### Data collection and analysis

LT and JP developed a topic schedule [Figure 1] to guide the semi-structured interviews which was agreed with the wider research team. Interviews were conducted by LT and JP by telephone (n=1 parent); face-to-face (n=2, parent with PICU survivor) and focus group (n=13 young people from the former Medicines for Children Research Network. The time duration of interviews ranged from 30 – 60 minutes. The individual and focus group interviews were undertaken on separate occasions on the hospital site in a private room and refreshments were provided.

Participants volunteered to engage with us to develop and strengthen the research study. They verbally agreed to the interview being audio-recorded (and for the use of direct quotes to be used). All recordings were deleted when transcription was completed. Data were analysed by LT and checked by JP using content analysis to

seek answers to our consultation objectives (Elo & Kyngas 2007). NHS ethical

approval was not required as this was a consultation exercise in research design.

INVOLVE and NRES differentiate between research consultation and research

participation because individuals are not research participants, in the context of

consultation they are acting as specialist advisors (NIHR 2014).

## Recruitment

We used a variety of methods to recruit parents, PICU survivors and young people from across the United Kingdom. We sent leaflets requesting participation in this study to families who had previously expressed an interest in contributing to the design of future research undertaken in PICU [Figure 2]. Posters and leaflets were also distributed at a conference and were displayed in the parents' room of the PICU, the cardiac ward, and the cardiac outpatients department at one hospital. Requests for parental engagement were sent to ICU Baby Steps (a charity based in London) and the Paediatric Intensive Care Audit Network [PICANet] Parents and Families Group. Recognizing the difficulties for parents in attending face-to-face meetings and the power of social media, we set up a Yammer online discussion forum (password protected) for consultation. We did not approach families directly but rather tried to advertise widely for interested parents to approach us. The Young People's group, is an established consultation group that meets monthly, formerly under the remit of the Medicine for Children Research Network and is led by JP the Patient Liaison Coordinator. This established group of young people provides feedback on a number of studies that researchers bring to the group. We sought verbal consent from all parties to enable us to audio-record the discussions.

## Results

Our results are based on three sources of consultation..

- One joint interview (duration 30 mins) with a father and young person (male, 15 year old) that had spent eight weeks in the PICU three months prior to the

interview. The young person had been severely ill and had difficulty in weaning off the ventilator.

- One focus group interview (duration 60 mins) with 13 young people who were members of the NIHR Clinical Research Network: Children, Young Person's Advisory Group. The group has a membership of 24 young people between the ages of 9-18 years old. Thirteen young people attended this meeting (average age 15, 10 females 3 males), none had experience of being in a PICU.
- One telephone interview (duration 30 mins) with a mother whose child had been in various PICUs multiple times over 10 years ago. Her daughter was born prematurely and had various health problems involving many periods of invasive ventilation, which had been stressful for the family

### **Relevance and importance of a trial of ventilation weaning**

All consultees agreed this would be an important study to undertake as it would lead to greater consistency in practice. In particular, when reflecting on the practice of weaning his son from ventilation, the father highlighted a perceived lack of consistency in ventilation weaning practice among staff. He reasoned that having a protocol would be helpful to staff, including doctors in training.

*"It did seem when we were on ICU it was quite random how [son's] ventilation was altered. I mean Dr XX would come in crank it [ventilation support] right down and then someone else would come scuttling in and turn it back up again". (Father)*

## Young person and parent-relevant outcome measures in a trial of ventilation

### weaning

In terms of the most relevant outcome measure for this trial, consultees agreed that duration of time on the ventilator was the most important thing to them. They recognised that the longer the time spent on ventilation, the longer the need for sedation. The PICU survivor explained: *“the quicker you get off the sedation the less side effects you will have”*. The father and son also believed that the risks associated with sedation were really important to highlight to parents in information about the trial.

## Parental and young people’s view on consent in this cluster RCT

In response to our question about whether it was necessary to gain formal written informed consent for this study and, if so, what information would be required for parents/patients, there was unanimous agreement that individual parental consent was unnecessary. As the mother explained:

*“all parents are concerned about is the prognosis, we don’t want to read and sign papers that don’t mean anything to us. Just give us the facts. If you are not doing any additional tests or procedures on my child, then it’s okay not to get us to sign consent forms and read lengthy pieces of information” [mother]*

The young people’s group felt the study would only require slightly more data collection about the child than already occurred and this would be unidentifiable.

*“It’s not like invasive is it? It’s not something they would really be against...” [YP]*

The consultees understood the nature of the research design (and what consent would relate to) and appreciated that it was a practice change rather than an alternative treatment. The opinion that consent was not required was linked to the design of the trial (cluster RCT) whereby all staff would be trained in the use of the protocol and all children would be weaned in this way. As one young person commented:

*“you can opt out of having the child’s additional data collected for the study but you can’t really opt out of the (weaning) protocol ...”* [in a cluster RCT] [YP]

However, consultees highlighted that despite not requiring written informed consent, information about the study should be made widely available in the PICU.

The young people’s group considered that having a poster displayed in the ward highlighting that the PICU was participating in the study would be sufficient. The mother suggested that the process should be explained in a “simplistic manner”. The father and son suggested that any information provided should describe the basic process about ventilation weaning, be informative without causing parental concern, and be clear about the use of the child’s data for study purposes explaining:

*“you might find that telling them [parents] stuff starts sowing seeds in their mind though...then they start to think ...well how long is my child going to be on ventilation and what is involved in coming off it...and they won’t think it is going to be an experimental thing, they will think everyone knows what they’re doing.....so it might sow some seeds of worry”* [Father and son]

## **Discussion**

Our PPI consultation showed that parents and young people considered this study important and relevant, and recommended that the most important outcome measure for them was the duration of ventilation. The duration of mechanical ventilation is one of the most frequently measured outcomes in trials of ventilation weaning [Blackwood et al 2014] and thus it was encouraging to know that it also held relevance for stakeholders.

The parents and young people did not believe that formal written informed consent was necessary due to the low level of risk. Giving information about research to parents of critically ill children requires care, as parents of critically ill children suffer from high levels of anxiety and this can impair their ability to comprehend important research concepts such as randomisation [Kanthimathinathan and Schofield 2014].

Studies in neonatal intensive care have indicated that obtaining prospective informed consent from parents who are stressed and anxious is problematic and can be flawed [Golec et al 2004; Ballard et al 2004; Featherstone & Donovan 2002].

These studies show that despite signing a consent form, many parents fail to recall their child being in a study and those who did recall this could not remember what the study was about [Golec et al 2004; Ballard et al 2004; Featherstone & Donovan 2002]. Thus, approaching parents for consent in a low risk cluster randomised trial of this nature, raises the question of whether we could do more harm than good by requesting parental consent. The parents and young people we engaged with felt this was unnecessary and consent would place a higher burden upon already stressed families. Notwithstanding, NHS ethics requirements are likely to require

parents to receive some information. The consultees' compromise seems a grounded and reasonable approach - a general display of information about the study in prominent parent areas - would allow parents to opt out of their child's data being collected and used for trial purposes. In the UK, a recent cluster RCT of a bedside paediatric early warning scoring (PEWS) tool did not require parental consent for participation (Parshuram et al 2015). This was because the new intervention (PEWS) was considered to be comparable to standard hospital practice with no increased risk of harm.

However, cluster RCTs raise a number of ethical and practical challenges that need to be considered relating to the unit of randomisation and consent; these include clinical equipoise and weighting of benefit and harm [Weijer et al 2011]. The choice for a cluster rather than a parallel group design in this trial was based on decisions to counteract the impact of cross contamination of intervention effects: once the team is trained, it would prove problematic to separate the effects of the protocol intervention from usual care

New HRA draft guidance [NHS Health Research Authority 2014] currently under consultation suggests that consent in cluster trials could be assumed from patients in a particular unit if there were clear displays in the unit that allowed patients to potentially opt out. Our consultation with our stakeholders supports this and they urged that any information provided should be short, simple and reassuring so not to add further anxiety about a low risk trial. The parents and young people were very pragmatic in their views about this type of trial.

Clinical equipoise can be described as genuine uncertainty about which treatment is better. In our case, 'usual' care around weaning sedation and ventilator practices across PICUs in the UK is inconsistent, reflecting the preferences of individual clinicians and the practices of individual units rather than being firmly evidence-based [Blackwood and Tume 2015]. In contrast to this inconsistent approach, the new team based protocol to guide sedation and ventilator weaning is derived from the literature and expert opinion. Our hypothesis is that the protocol would be superior in terms of reducing ventilation time compared to usual care, but we do not know this. From an ethical perspective, the protocol will not cause harm, but may not be beneficial. Indeed, these types of interventions are commonly brought into intensive care units in an informal manner as 'service improvement' with no formal rigorous evaluation and no patient consent. The introduction of a change in practice as part of a trial creates both a more formal means of implementation, informing parents and a more rigorous evaluation of its effectiveness.

### **Limitations and challenges**

Despite using a variety of recruitment methods to engage with as many patients and families with PICU experience as possible, recruitment was lower than expected and we found this extremely challenging. We received only one expression of interest from ICU Baby Steps (the charity) but no response when this was followed up. From the PICANet Parents' and Families' group, we received one response and conducted a telephone interview with this parent. The Yammer PICU parent's discussion group



was not successful in engaging with parents as it had been in previous research work and reasons for this are unclear. The father and his son (PICU survivor) were recruited from one hospital site and they had expressed an interest in participating in this consultation exercise. Thus, despite various methods to engage with parents and ex-patients, recruitment was low.

There are a variety of reasons which may explain low engagement of parents and young people. Face-to-face consultation may be difficult for parents who are geographically distant from the hospital undertaking the study. The majority of patients admitted to PICU are less than 12 months old [PICANET 2013]. This age profile means that most patients would not be either able or eligible to contribute their views within a consultation exercise. Many parents of children admitted to PICU are young, have other children to care for, are generally in employment and may not have time or energy to engage in consultation work (Bronner et al 2010). In comparison with the reported good levels of engagement with adult ICU survivors and carers who are older and/or retired (Adult Critical Care in HES: England, 2012) PICU demographics are very different. We acknowledge that due to the small representation, the views presented here are not necessarily generalizable.

However, despite these limitations, the information we gathered has been particularly useful in the design of the study. We also gained experience and insight to the challenges we will need to address in future consultation work with this important but difficult to access population of parents and PICU survivors.

## **Conclusions**

The drive for patient and public involvement in healthcare overall is important. Through our consultation work we gained valuable insights into important issues in the preparation of our trial of ventilation weaning. Once we had recruited participants, the actual consultation work was relatively straightforward and we were able to draw on our interviewing skills to generate useful data. The main challenge related to recruiting parents and PICU survivors; adequate recruitment is likely to be a barrier in future consultation work. The absence of a national support group for 'PICU parents' increases the difficulty of accessing parents (who have experienced a PICU episode) in a timely way. The methods we used, face-to-face and telephone interviews worked well with the parents who participated but we need to consider more novel ways in which parents with family and work responsibilities can also engage. Despite these challenges, we would strongly advocate the benefits of PPI work both in service improvement and also in research design.

#### **What is known about this topic?**

- PPI work is important and encouraged in the development of all healthcare studies
- PPI work is important to ensure that research questions and outcome measures are relevant and meaningful to patients and parents

#### **What this paper adds**

- It has highlighted the challenges of engaging with parents of ex-PICU patients and children for to improve research design

- Paediatric intensive care researchers need to find more novel ways to engage with parents of PICU survivors to develop parent/patient-relevant research trials

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